



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/867,819	04/13/92	HARLEY	12

18M1/1202

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CAE EXAMINER

ART UNIT 17 PAPER NUMBER

90
12/02/96

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 07/867,819	Applicant(s) Harley, J. B.
	Examiner Anthony C. Caputa	Group Art Unit 1817

Responsive to communication(s) filed on Aug 30, 1996

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-3 and 10-16 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-3 and 10-16 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The finality of the Office action mailed 8/15/95 is withdrawn (see Paper No. 31). All outstanding rejections are withdrawn in view of applicants arguments and further consideration by the Examiner.
2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1817.
3. The amendment changing "45*-48" to "41*-48" on page 18, line 14 as set forth on applicant's preliminary amendment received 9/13/93 (Paper No. 12) was not entered since "45*-48" was not found on page 18, line 14 as indicated. Similarly the amendment changing "215-222" to "216-223" on page 18, line 27 as set forth on applicant's preliminary amendment received 9/13/93 (Paper No. 12) was not entered since "215-222" was not found on page 18, line 14 as indicated.

Specification

4. The amendment filed 9/22/93 (Paper No. 12) is objected to under 35 U.S.C. 132 because

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introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

A. The modification of amino acid sequence of the peptide as set forth on page 6, line 6; page 14, line 6; page 18, line 21; page 18, line 35; page 18, line 44; page 19, line 22; page 19, line 23; page 19, line 28; page 19, line 29; page 20, line 5.

B. The modification of the Sequence Listing Nos. 6, 22, 48, 62, 71, 74, 75, 85, 90, and 94. (See page 33 of applicant's amendment filed 9/22/93).

Applicants set forth in their amendment that the changes were made solely for the purpose of correcting typographical errors. Said argument is not persuasive to overcome the objection since the specification as originally filed provides no support for these changes.

Applicant is required to cancel the new matter in the response to this Office action.

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent

Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

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6. Sequence rules set forth in 37 C.F.R. § 1.821 require the use of SEQ ID No if the sequence is embedded in the text or in the claims. All sequences must be referred to by use of an identifier such as "SEQ ID NO" as presented in the Sequence Listing even though the sequence itself may be imbedded in the text of the application.

Claim Rejections - 35 USC § 112

7. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 16 are rejected for lack of antecedent basis for the term "patient sample". To obviate this rejection the Examiner suggest using the phrase "biological sample".

Claim 16 is rejected for lack of antecedent basis for the term "Ro/SSA peptides".

8. Claims 1-3, and 10-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for modification of the sequence of the amino acid sequence of the Ro/SSA epitopes which start at 165, ALAVTK...LSH; 169, TKYKORNG; 173, QRNGWSHK; 379, ASMNQRVLGS.

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9. Any inquiry concerning this communication should be directed to Dr. Anthony C. Caputa, whose telephone number is 703-308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is 703-308-0196.

Papers related to this application may be submitted to Group Art Unit 1817 by facsimile transmission. Papers should be faxed to Group Art Unit 1817 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703)-308-4242.

Anthony C. Caputa, Ph.D.
November 24, 1996

AC

ANTHONY C. CAPUTA
PRIMARY EXAMINER
GROUP 1800

PH

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER
GROUP 1800

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG May 15, 1990 and at 55 FR 18230, May 1, 1990.

2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirement of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

7. Other: This application fails to comply with these requirements since there is no seq listing for PPPPP (see page 2, of the specification)
Applicant must provide:

An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

A statement that the content of the paper and computer readable copies are the same, and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123

For CRF submission help, call (703) 308-4212

For PatentIn software help, call (703) 557-0400